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PTO/SB/05 (4/98)
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Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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UTILITY PATENT APPLICATION TRANSMITTAL

Only for new nonprovisional applications under 37 C F R. § 1. 53(b))

Attorney Docket No.	PA066
First Inventor or Application Identifier	Aboul-Hosn
Title	SINGLE PORT CARDIAC SUPPORT APPARATUS
Express Mail Label No.	EL514049149US

APPLICATION ELEMENTS

*See MPEP chapter 600 concerning utility **patent application contents.***

ADDRESS TO: **Assistant Commissioner** for Patents
Box Patent Application
Washington DC 20231

1. [X] • Fee Transmittal Form (e.g. PTO/SB/17)
(Submit an original and a duplicate for fee processing)

2. [X] Specification *[Total Pages* 22]
(preferred arrangement set forth below)
- Descriptive title of the Invention
- Cross References to Related Applications
- Statement Regarding Fed sponsored R & D
- Reference to Microfiche Appendix
- Background of the Invention
- Brief Summary of the Invention
- Brief Description of the Drawings (if *filed)*
- Detailed Description
- Claim(s)
- Abstract of the Disclosure

3. [X] Drawing(s) (35U.S.C. 113) *[Total Sheets* 5]

4. Oath or Declaration *[Total Pages* 27]
a. [X] Newly executed (original or copy)
b. [ ] Copy from a prior application (37 C.F.R. § 1.63(d))
(for continuation/divisional with Box 16 completed)
i. [ ] **DELETION OF INVENTOR(S)**
Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

• NOTE FOR ITEMS 1& 13: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C FR §128)

5. [ ] Microfiche Computer Program **(Appendix)**

6. Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)
a. [ ] Computer Readable Copy
b. [ ] Paper Copy (identical to computer copy)
c. [ ] Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

7. [ ] Assignment Papers (cover sheet & document(s))
8. [ ] 37 C.F.R.§3.73(b) Statement *(when there is an assignee)* [ ] Power of Attorney
9. [ ] English Translation Document *(if applicable)*
10. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
11. [ ] Preliminary Amendment
12. [X] Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
13. [ ] • Small Entity Statement(s) **(PTO/SB/09-12)** [X] Statement filed in prior application, Status still proper and desired
14. [ ] Certified Copy of Priority Document(s)
(if foreign priority is claimed)
15. [ ] Other: _____

16. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in a preliminary amendment-*
[ ] Continuation [X] Divisional [ ] Continuation-in-part (CIP) of prior application No: 08 /891,456
Prior application Information.- Examiner Tram Nguyen *Group I Art Unit-* 3738
For CONTINUATION or DIVISIONAL APPS only : The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can oni be relied upon when a portion has been inadvertently omitted from the submitted application parts.

17. CORRESPONDENCE ADDRESS

[X] *Customer Number or Bar Code Label* (Insert Customer No. or Attach bar code label here) 23710 or [X] *Correspondence address below*

Name	Jonathan Spangler, Esq.				
	PATENT TRADEMARK OFFICE				
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City	West Sacramento	*State*	California	*Zip Code*	95691
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Name (Print/Type)	Jonathan Spangler, Esq.	*Registration No (Attorney/Agent)*	40,182
Signature		*Date*	September 25, 2000

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231.

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FEE TRANSMITTAL for FY 1999

Patent fees are *subject to* annual revision.
Small *Entity payments* must be supported by a small entity statement, otherwise large entity fees must be paid. See *Forms* PTO/SB/09-12.
See 37 *C.F.R. §§* 1.27 *and* 1.28.

TOTAL AMOUNT OF PAYMENT ($)

Complete if Known	
Application Number	N/A
Filing Date	September 25, 2000
First Named Inventor	Aboul-Hosn
Examiner Name	N/A
Group /Art Unit	N/A
Attorney Docket No.	PA066

jc844 U.S. PTO 09/669104 09/25/00

METHOD OF PAYMENT (check one)

1. ☒ The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:

Deposit Account Number: 50-1026

Deposit Account Name: A-Med Systems, Inc.

☒ Charge Any Additional Fee Required Under 37CFR§§ 1 16 and 1 17

2. ☐ **Payment Enclosed:** ☐ Check ☐ Money Order ☐ Other

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code ($)	Small Entity Fee Code ($)	Fee Description	Fee Paid
101	760 201 380	Utility filing fee	$345
106	310 206 155	Design filing fee	
107	480 207 240	Plant filing fee	
108	760 208 380	Reissue filing fee	
114	150 214 75	Provisional filing fee	

SUBTOTAL (1) ($) 345

2. EXTRA CLAIM FEES

	Extra Claims		Fee from below	Fee Paid
Total Claims	17 -20** =	X		0
Independent Claims	3 - 3**= 0	X		0
Multiple Dependent			0	0

-or *number previously* paid, if greater; For Reissues, see below

Large Entity Fee Code ($)	Small Entity Fee Code ($)	Fee Description
103	18 203 9	Claims in excess of 20
102	**78 202 39**	**Independent claims in excess of 3**
104	**260 204 130**	**Multiple dependent claim, if not paid**
109	**78 209 39**	**** Reissue independent claims over original patent**
110	**18 210**	**** Reissue claims in excess of 20 and over original patent**

SUBTOTAL (2) ($) 0

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code ($)	Small Entity Fee Code ($)	Fee Description	Fee Paid
105	130 205 65	Surcharge - late filing fee or oath	
127	50 227 25	Surcharge - late provisional filing fee or cover sheet	
139	130 139 130	Non-English specification	
147	2,520 147 2,520	For filing a request for reexamination	
112	920* 112 920*	Requesting publication of SIR prior to Examiner action	
113	1,840* 113 1,840*	Requesting publication of SIR after Examiner action	
115	110 215 55	Extension for reply within first month	
116	380 216 190	Extension for reply within second month	
117	870 217 435	Extension for reply within third month	
118	1,360 218 680	Extension for reply within fourth month	
128	1,850 228 925	Extension for reply within fifth month	
119	300 219 150	Notice of Appeal	
120	300220 150	Filing a brief in support of an appeal	
121	260 221 130	Request for oral hearing	
138	1,510 1381,510	Petition to institute a public use proceeding	
140	110 240 55	Petition to revive - unavoidable .	
141	1,210 241 605	Petition to revive - unintentional	
142	1,210 242 605	Utility issue fee (or reissue)	
143	430 243 215	Design issue fee	
144	580 244 290	Plant issue fee	
122	130 122 130	Petitions to the Commissioner	
123	50 123 50	Petitions related to provisional applications	
126	240 126 240	Submission of Information Disclosure Stmt	
581	40 581 40	Recording each patent assignment per property (times number of properties)	
146	760 246 380	Filing a submission after final rejection (37 C.F.R § 1.129(a))	
149	760 249 380	For each additional invention to be examined (37 C.F.R § 1.129(b))	

Other fee (specify) _____

Other fee (specify) _____

* Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 0

SUBMITTED BY

					Complete (if applicable)
Name (Print/Type)	Jonathan Spangler, Esq.	*Registration No.* (Attorney/Agent)	40,182	Telephone	(916) 375-7400, Ext. 301
Signature				Date	September 25, 2000

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VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) AND 1.27 (b)) - INDEPENDENT INVENTOR

Docket No. ABOU 102

Serial No.	Filing Date	Patent No.	Issue Date

Applicant/ Patentee: **Walid N. Aboul-Hosn**

Invention: **SINGLE PORT CARDIAC SUPPORT APPARATUS**

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled above and described in:

- ☒ the specification to be filed herewith.
- ☐ the application identified above.
- ☐ the patent identified above.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☒ No such person, concern or organization exists.
- ☐ Each such person, concern or organization is listed below.

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities (37 CFR 1.27)

FULL NAME _____

ADDRESS _____

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME _____

ADDRESS _____

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FULL NAME _____

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FULL NAME _____

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I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF INVENTOR **Walid N. Aboul-Hosn**
SIGNATURE OF INVENTOR Walid Aboul-Hosn DATE: 6/20/97

NAME OF INVENTOR ______
SIGNATURE OF INVENTOR ______ DATE: ______

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SIGNATURE OF INVENTOR ______ DATE: ______

SINGLE PORT CARDIAC SUPPORT APPARATUS

This application is a divisional of application under 37 CFR 1.53(b) of pending U.S. Patent Application Ser. No. 08/891,456 filed on July 11, 1997.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to apparatus and method for providing cardiac support during cardiac surgery. More particularly, the present invention relates to such apparatus and method for providing cardiac support which are less traumatic and invasive.

2. Description of the Related Art

When it is necessary to perform cardiac surgery, surgery has heretofore been accomplished by major open-heart surgical procedure, requiring general anesthesia and full cardio-pulmonary bypass (CPB). Such surgery usually includes about three weeks of hospitalization and months of recuperation. Average mortality rate for this procedure is approximately 1% with complication rate being substantially higher. Descriptions of open heart procedure can be found in *Gibbon's* Surgery of the Chest 5th Edition, (David C. Sabiston, Jr., M.D., Frank D. Spencer, M.D. 1990, Vol. 11, Ch. 52, pp. 1, 56-61, 596, and Textbook of Interventional Cardiology, Eric. J. Topol, 1990, Chs. 43-44, pp. 831-867).

Coronary artery bypass graft (CABG) procedure is one type of open chest surgical technique used to treat coronary artery disease. During the CABG procedure, the patient's sternum must be opened with the chest spread apart to provide access to the heart. The patient's blood is cooled and diverted from the patient's lung to an artificial oxygenator. A source of arterial blood is then connected to a coronary artery downstream from the occlusion while the patient undergoes cardiac arrest and is supported by a CPB circuit. The source of blood is often the left or right internal mammary artery and the target coronary artery is the anterior or posterior arteries which might be narrowed or occluded.

While very effective in many cases, the use of open chest surgery is very traumatic to the patient. The procedure requires immediate post-operative care in an intensive care unit. The total period for hospitalization may be seven to ten days, while the total recovery period may be as long as six to eight weeks. In addition, open-heart procedure requires the use of CPB which continues to represent a major assault on a host of body systems. For example, in up to 24% of the open chest coronary artery bypass surgeries performed in the United States, there is a noticeable degradation of the patient's mental faculties following such surgeries. This degradation is commonly attributed to cerebral arterial blockage from debris and emboli generated during the surgical procedure.

In addition, much post-operative morbidity, and some mortality, is attributed to the shortcomings of CPB.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide an apparatus which provides cardiac support during cardiac surgery.

It is another object of the present invention to provide such an apparatus which is less traumatic and invasive to the patient than current apparatuses used today.

It is a further object of the present invention to provide a method for providing cardiac support using the features described herein.

These and other objects are met by providing an apparatus that is used extravascularly, possibly trans-valvularly, and requires only one incision into a major blood vessel or heart chamber. The apparatus includes an elongated inner cannula which is inserted through a portal formed in a major blood vessel or heart chamber. Disposed coaxially over the inner cannula is an outer conduit or cannula. A blood pump, such as the reverse flow blood pump disclosed herein, is communicatively coupled between the proximal openings on the inner cannula and outer conduit. The blood pump may be selectively operated to pump blood from the distal end

of one cannula to the distal end of the other cannula. The distal openings on the inner cannula and outer conduit are spaced apart and disposed either in different blood vessels or transvalvularly in the heart.

In this fashion, the apparatus of the present invention may be used in both right-heart and left-heart support applications. For right-heart cardiac support, by way of example only, the outer cannula may be secured within a portal formed in the wall of the pulmonary artery such that its distal opening is positioned within the pulmonary artery, while the inner cannula is extended through the outer conduit and pulmonic valve such that its distal opening is positioned within the right ventricle. The blood pump may then be operated to re-route blood from the right ventricle into the pulmonary artery to assist or replace right-heart function. For left-heart cardiac support, by way of example only, the outer conduit may be secured within a portal formed in the wall of the aorta such that its distal opening is positioned within the aorta, while the inner cannula is extended through the outer cannula, the aortic valve, the left ventricle, and the mitral valve such that its distal opening is positioned in the left atrium. The blood pump may then be operated to re-route blood from the left atrium into the aorta to assist or replace left-heart function.

Optional balloons may be selectively inflated on the outside surface of the inner cannula or outer

conduit which act to seal off the passageway between the sides of the blood vessel and the cannula, to cool adjacent tissue, or to deliver drugs to adjacent tissue.

A method of providing cardiac support is also provided which involves the features set forth above regarding the apparatus of the present invention.

Other objects and advantages of the present invention will become apparent from the following description of the preferred embodiments taken in conjunction with the accompanying drawings wherein like parts in each of the several figures are identified by the same reference characters.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view, partially in section, of the cardiac support apparatus disclosed herein being installed through a portal formed in the major blood vessel with the distal opening of the outer conduit disposed just inside the portal and the inner cannula being disposed transvalvularly in a heart chamber;

FIG. 2 is a side elevational view, partially in section, of the cardiac support apparatus;

FIG. 3 is a sectional view of the apparatus taken along lines 3—3 in Fig. 2;

FIG. 4 is an exploded, perspective view of the pump's housing body with an inlet tube and base plate;

FIG. 5 is a side elevational view of the rotor;

FIG. 6 is an illustration of the heart showing a portal formed in the pulmonary artery with the distal end of the outer conduit extending therethrough and the inner cannula being extending through the pulmonic valve and terminating in the right ventricle; and

FIG. 7 is an illustration of the heart showing a portal formed in the aorta with the distal end of the outer conduit extending therethrough and the inner cannula being extended through the aortic valve, left ventricle, and mitral valve and terminating in the left atrium.

DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

Referring to accompanying Figs. 1-7, therein is shown a cardiac support apparatus, generally referred to as 10, designed to provide cardiac support (right-heart and/or left-heart) during cardiac surgery. The cardiac support apparatus 10 of the present invention generally includes an inner conduit or cannula 20, an outer conduit or cannula 30, and a blood pump 50. The inner cannula 20 has a distal opening 22 that, in use, is positioned to extend past the distal opening 32 of the outer conduit 30. The blood pump 50 is communicatively coupled between the inner cannula 20 and outer conduit

30 to selectively transport blood from one distal opening to the other distal opening. By using such an arrangement, only one portal is required into a major blood vessel or heart chamber.

In the embodiments shown herein, the inner cannula 20 is shown and described as an inlet conduit designed to deliver blood to the pump 50 while the outer conduit 30 is designed to transport blood away from the pump 50. It should be understood, however that the relative functions of the inner cannula and outer conduit may be exchanged depending on the desired positions of the distal openings of the inner cannula 20 and outer conduit 30 and the direction of the flow of blood by the pump 50.

The inner cannula 20 has a distal opening 22 and a proximal opening 24. During use, the distal opening 22 is disposed in a major blood vessel, such as the aorta or in the right ventricle 97 as shown in Fig. 6. When blood enters the distal opening 22, it is transported through the inner cannula 20 to the pump 50. The pump 50 then forces the blood through the outer conduit 30 to a downstream located blood vessel or chamber.

The inner cannula 20 is tubular and preferably made of flexible, bio-compatible material such as silicone, and reinforced with other material, such as steel wire, to provide sufficient radial stiffness to resist collapsing. The tip 25 of the inner cannula 20 is not

reinforced and chambered to provide greater flexibility to improve advancement of the inner cannula 20 through small vessels or chambers and prevent trauma to surrounding tissue. Inner cannula 20 has a plurality of orifices 27 formed near its tip 25 to allow blood to flow into the inner cannula 20 when the distal opening 22 is occluded. During use, a catheter or guide wire can also be extended through the opening 24 which enables the inner cannula 20 to be disposed at a desired location in the body. The inner cannula 20 can have a permanent bend formed therein curved 10 and 20 degrees to facilitate installation and removal from a blood vessel or chamber. The inner cannula 20 may also have radiopaque material added or printed on its surface of visibility when exposed to X-ray radiation.

The outer conduit 30 is tubular and made of flexible, bio-compatible material such as silicone, and reinforced with other material, such as steel wire, to provide sufficient radial stiffness to resist collapsing. The outer conduit 30 has a sufficient inside diameter so that the inner cannula 20 may be coaxially aligned therein and a blood flow passage 65 is created between the outside surface of the inner cannula 20 and the inside surface of the outer conduit 30. In the embodiment shown in Fig. 1, the distal opening 32 of the outer conduit 30 is extended through a portal 91 thereby creating a closed circuit between the inner cannula 20 and outer conduit 30. In the preferred embodiment, the outer conduit 30 is an introducer, a

cannula, or a vascular graft, such as DACRON™ graft, or any other vascular graft available commercially and used for anastomosis.

The pump 50 is, by way of example only, a reverse axial flow pump with coaxially aligned inlet and outlet ports formed therein. Pump 50 includes a rotor 70 axially aligned inside a cylindrical-shaped housing body 52. The rotor 70 is connected to a drive shaft 81 which is rotated at high speed by the driving unit 80. The distal opening of the housing body 52 is covered with a housing cap 60. The housing cap 60 is preferably made of stainless steel or a rigid polymer with a plurality of outflow windows 64 formed therein. The outflow windows 64 are radially aligned around the inlet neck 62. The housing body 52 is cylindrical-shaped and includes a longitudinally aligned inlet tube 55. The inlet tube 55 is integrally attached at one end to the base plate 53 and includes a centrally aligned distal opening 56 and a plurality of radially aligned cut-outs 57. Disposed longitudinally inside the inlet tube 55 is the rotor 70.

During operation, the rotor 70 is rotated which forces blood delivered to the inlet tube 55 through the cut-outs 57. The outside diameter of the inlet tube 55 is smaller than the inside diameter of the housing body 52 thereby creating a passageway 59 between the inlet tube 55 and the housing body 52. Attached over the distal opening of the housing body 52 is a housing cap

60. The housing cap 60 includes a circular base member 61 designed to attach tightly over the housing body 52. A cylindrical inlet neck 62 is perpendicular and centrally aligned on the base member 61. A plurality of outflow windows 64 are radially aligned on the base member 61 outside the inlet neck 62. The outer diameter of the inlet neck 62 is smaller than the inside diameter of the outer conduit 30 thereby creating a second passageway 65 for blood to flow through. The passageway 59 and the outflow windows 64 of the housing cap 60 are aligned when the housing cap 60 and the housing body 52 are assembled.

As shown in Figs. 1 and 2, the apparatus 10 is assembled in an optional elongated, cylindrical body 40 which connects to the proximal opening 34 of the outer conduit 30 designed to house the pump 50 and the drive unit 809. During use, the cylindrical body 40 acts as a handle to enable the apparatus 10 to be placed in a desired location. In other embodiments, not shown, the pump 50 may be sealed and attached to the outer conduit 30 with the drive unit 80 located externally.

During installation, the distal openings 22, 32, of the inner cannula 20 and outer conduit 30, respectively, are adjusted to be spaced apart and located in different blood vessels or opposite sides of a heart valve thereby enabling blood to be pumped from one blood vessel or chamber to another. The inner cannula 20 and outer conduit 30 are coaxially aligned and have sufficient

length so that only one portal opening is required into the major blood vessel or chamber.

The placement of the apparatus 10 requires the anastomosis of the distal end of the outer conduit to the sides of the targeted blood vessel or chamber using thoracoscopic suturing, or microstapling. Prior to suturing the outer conduit 30 to the blood vessel, the blood vessel can be isolated using a " C" clamp or the use of thoracoscopic clamps best described in Evard, P. et al. in U.S. Patent No. 5,425,705 or similar clamps capable of passing small ports on the patient's body and could isolate a section of a vessel without complete occlusion of the vessel in question.

Fig. 6 is an illustration of the cardiac support apparatus 10 being used to provide cardiac support to the right side of the heart by pumping blood from the right ventricle 97 to the pulmonary artery 98. In this instance, a portal 91 is formed in the pulmonary artery 98 through which the distal end of the outer conduit 30 is extended. The inner cannula 20 is then inserted into the portal 91, through the pulmonic valve 95 and into the right ventricle 97. It will be appreciated that this same right-heart cardiac support could be accomplished (and is contemplated as being part of the present invention) by securing the outer conduit 30 within a portal formed in the wall of the right atrium, right ventricle, or atrial appendage such that its distal end is positioned in the right atrium or right

ventricle, while the inner cannula 20 is extended therethrough such that its distal end is positioned within the pulmonary artery. In this arrangement, the pump 50 would reroute blood from the outer conduit 30 into the inner cannula 20 for delivery into the pulmonary artery for right-heart cardiac support.

Fig. 7 is an illustration showing the apparatus 10 with the outer conduit 30 being attached to a portal 91 formed in the aorta 92 and the inner cannula 20 being extended through the portal 91, then the aortic and mitral valves 96, 99, respectively, and into the left atrium. It will be appreciated that this same left-heart cardiac support could be accomplished (and is contemplated as being part of the present invention) by securing the outer conduit 30 within a portal formed in the wall of the left atrium or left ventricle such that its distal end is positioned in the left atrium or left ventricle, while the inner cannula 20 is extended therethrough such that its distal end is positioned within the aorta. In this arrangement, the pump 50 would reroute blood from the outer conduit 30 into the inner cannula 20 for delivery into the aorta for left-heart cardiac support.

After the portal is created in the desired blood vessel, the outer conduit 30 is then inserted into the portal 91. A suture may be used to hold the outer conduit 30 inside the portal 91. A commercially available high stiffness guide wire may be passed

through the outer conduit 30 to which the inlet cannula 20 and pump 50 are attached. The length of the outer conduit 30 must be sufficiently long to accommodate the pump 50. After placing the pump 50 in the outer conduit 30, the outer conduit 30 is filled with a saline solution, the pump 50 is primed if necessary, and air is completely removed from the pump 50 and the outer conduit 30. The driving unit 80 is then installed over the proximal end of the pump 50. A silicone plug or similar hemostasis valve must be used to seal the outer conduit 30 if the driving unit 80 is located externally.

After the installation is completed, the " C" clamp is released gradually and hemostasis at all possible bleeding sites are examined visually or with the aid of a viewing scope inserted into the body. Assuming acceptable hemostasis is achieved, then the " C" clamp 300 may be completely released but kept in a position to clamp the anastomosis site in case of emergency.

At this point, the guide wire can be advanced with the help of imaging techniques to dispose the distal end of the inlet cannula 20 in the desired blood vessel or heart chamber. While positioning the distal end of the inlet cannula 20, the pump 50 may need to be advanced in the outer conduit 30 by pushing the positioning rod into the outer conduit 30. A suture or laproscopic clamping device may then be used to hold the apparatus in place. After securing the apparatus 10, the guide wire is removed from and the pump 50 is activated to initiate

blood pumping.

After the pump 50 is activated, a drug known to slow or completely stop the heart can be administered as required. The pumping rate of the pump 50 is then adjusted to maintain sufficient circulation. The pumping rate can also be adjusted to accommodate changes in the circulatory demand. The pump 50 can also be equipped with means (not shown) for measuring blood pressure, the presence of blood at the tip of the inner cannula, or other parameters that could indicate to the treating physician if a change in speed is required. Also, the apparatus 10 may include sensors (not shown) that sense the pressure at the proximal distal opening of the inner cannula 20, wherein a preset pressure change could signal the need to change the pumping capacity of apparatus 10. For example, when the pressure at the distal end of inner cannula 20 decreases by a certain degree, which indicates the commencement of pump suction, a controller used with the apparatus 10 could signal the user or automatically decrease the pump speed to return to a pre-selected pressure at the inner cannula 20.

To remove the apparatus 10, the suture or laproscopic clamping device is first disconnected enabling the apparatus 10 to move. The pump 50 and inner cannula 20 is retracted though the outer conduit 30, the " C" clamp 300 is clamped, thoracoscopically the anastomosis is restored using common thoracoscopic

techniques for suturing or stapling, then anastomosis is removed and the patient's skin would is closed using known techniques for wound closure.

Also, as shown in Fig. 7, an optional balloon 85 may be disposed on the outside surface of the inner cannula 20 to seal, or to deliver a cool fluid or medication to the adjacent tissue. The balloon 85 is disposed around the inner cannula 20 and connected to a conduit 86 through which air, a suitable coolant, or medication may be transported to the balloon 85. When the balloon 85 is used to deliver medication, a plurality of perforations 87 may be formed on the surface of the balloon 85 to allow medication to be delivered to the surrounding tissue.

Using the above described apparatus, a method of providing cardiac support is also provided which includes the following steps:

a. selecting a blood flow apparatus including a generally coaxially aligned and slideably arranged inner conduit and outlet conduit, and a blood pump disposed therebetween, the blood pump capable of pumping blood through a body;

b. forming a portal in a blood vessel or heart chamber;

c. securing the outer conduit within the portal;

d. inserting the inner conduit through the portal so that the distal opening of the inner cannula is disposed on an opposite side of a desired heart valve as

the distal opening of the outer conduit; and

e. activating the pump so that blood is pumped into the distal opening of one of the inner conduit and outer conduit and transported out of the distal opening of the other of the inner conduit and outer conduit.

In compliance with the statute, the invention, described herein, has been described in language more or less specific as to structural features. It should be understood, however, the invention is not limited to the specific features shown, since the means and construction shown comprised only the preferred embodiments for putting the invention into effect. The invention is, therefore, claimed in any of its forms or modifications within the legitimate and valid scope of the amended claims, appropriately interpreted in accordance with the doctrine of equivalents.

CLAIMS

I claim:

1. A method of providing cardiac support comprising the steps of:

a. selecting a blood flow apparatus including a generally coaxially aligned and slideably arranged inner conduit and outlet conduit, and a blood pump disposed therebetween, the blood pump capable of pumping blood through a body;

b. forming a portal in a blood vessel or heart chamber;

c. securing the outer conduit within the portal;

d. inserting the inner conduit through the outer conduit so that the distal opening of the inner cannula is disposed on an opposite side of a desired heart valve as the distal opening of the outer conduit; and

e. activating the pump so that blood is pumped into the distal opening of one of the inner conduit and outer conduit and transported out of the distal opening of the other of the inner conduit and outer conduit.

2. The method of claim 1 and further, wherein the blood pump is a reverse axial flow blood pump.

3. The method of claim 1 and further, wherein the distal openings of the inner and outer conduits are positioned on either side of the pulmonic valve and the pump operated to provide right-heart cardiac support.

4. The method of claim 1 and further, wherein the distal openings of the inner and outer conduits are positioned on either side of the aortic valve and the pump operated to provide left-heart cardiac support.

5. A method of treating heart tissue during cardiac surgery, comprising the steps of:

a. providing a cannula dimensioned to extend into a heart chamber during cardiac surgery;

b. equipping the cannula with at least one inflatable member; and

c. providing a fluid source capable of inflating the inflatable member.

6. The method of claim 5 and further, wherein the fluid source comprises a fluid having coolant properties to cool the adjacent heart tissue upon inflation of the inflatable member.

7. The method of claim 5 and further, wherein the inflatable member has at least one perforation and the fluid source comprises a fluid having medicament properties such that medication may be delivered to the adjacent heart tissue upon inflation of the inflatable member.

8. The method of claim 5 and further, wherein the cannula is equipped with a first inflatable member at a first location along the cannula and a second inflatable member at a second location along the cannula.

9. The method of claim 8 and further, wherein the first and second inflatable members are disposed on either side of at least one heart valve and inflated to seal off the blood flow along the exterior of the cannula between the first and second location.

10. The method of claim 9 and further, wherein the first inflatable member is positioned downstream from the aortic valve, the second inflatable member is positioned upstream from the mitral valve, and the first and second inflatable members inflated such that blood from the left atrium passes through the interior of the cannula for delivery into the aorta.

11. The method of claim 10 and further, wherein the flow of blood from the left atrium into the aorta is facilitated by a blood pump.

12. A system for providing cardiac support during surgery, comprising:

a. a blood pump having an inlet port and an outlet port;

b. a first conduit having a proximal opening and a distal opening, the proximal opening coupled to the inlet port of the blood pump, and the first conduit being dimensioned such that the distal opening may extend into a heart chamber or vessel;

c. a second conduit having a proximal opening and a distal opening, the proximal opening coupled to the outlet port of the blood pump, and the second conduit disposed generally coaxially relative to the first conduit and dimensioned such that the distal opening of the second conduit is spaced-apart from the distal end of the first conduit within the heart or vessel;

d. at least one inflatable member disposed along at least one of the first conduit and the second conduit; and

e. a fluid source capable of inflating the inflatable member.

13. The system of claim 12 and further, wherein the fluid source comprises a fluid having coolant properties to cool the adjacent heart tissue upon inflation of the inflatable member.

14. The system of claim 12 and further, wherein the inflatable member has at least one perforation and the fluid source comprises a fluid having medicament properties such that medication may be delivered to the adjacent heart tissue upon inflation of the inflatable member.

15. The system of claim 12 and further, wherein the first conduit is equipped with a first inflatable member at a first location and a second inflatable member at a second location.

16. The system of claim 15 and further, wherein the first and second inflatable members are disposed on either side of at least one heart valve and inflated to seal off the blood flow along the exterior of the first conduit between the first and second location.

17. The system of claim 16 and further, wherein the first inflatable member is positioned downstream from the aortic valve, the second inflatable member is positioned upstream from the mitral valve, and the first and second inflatable members inflated such that blood from the left atrium passes through the interior of the first conduit for delivery into the aorta.

ABSTRACT OF THE DISCLOSURE

A minimal intrusive cardiac support apparatus is disclosed which requires only one incision into a main blood vessel or heart chamber. The apparatus includes a pair of generally coaxial and slideably arranged cannulae (one inner and one outer) communicatively coupled to a blood pump for providing right-heart and/or left-heart cardiac support during cardiac surgery. Optional balloons may be mounted on the outside of the inner and outer conduits which can be selectively inflated to seal off the sides surrounding vessel or to deliver cooling fluid or medication to the surrounding tissue. Using the apparatus, a method of pumping blood through the body is also disclosed.

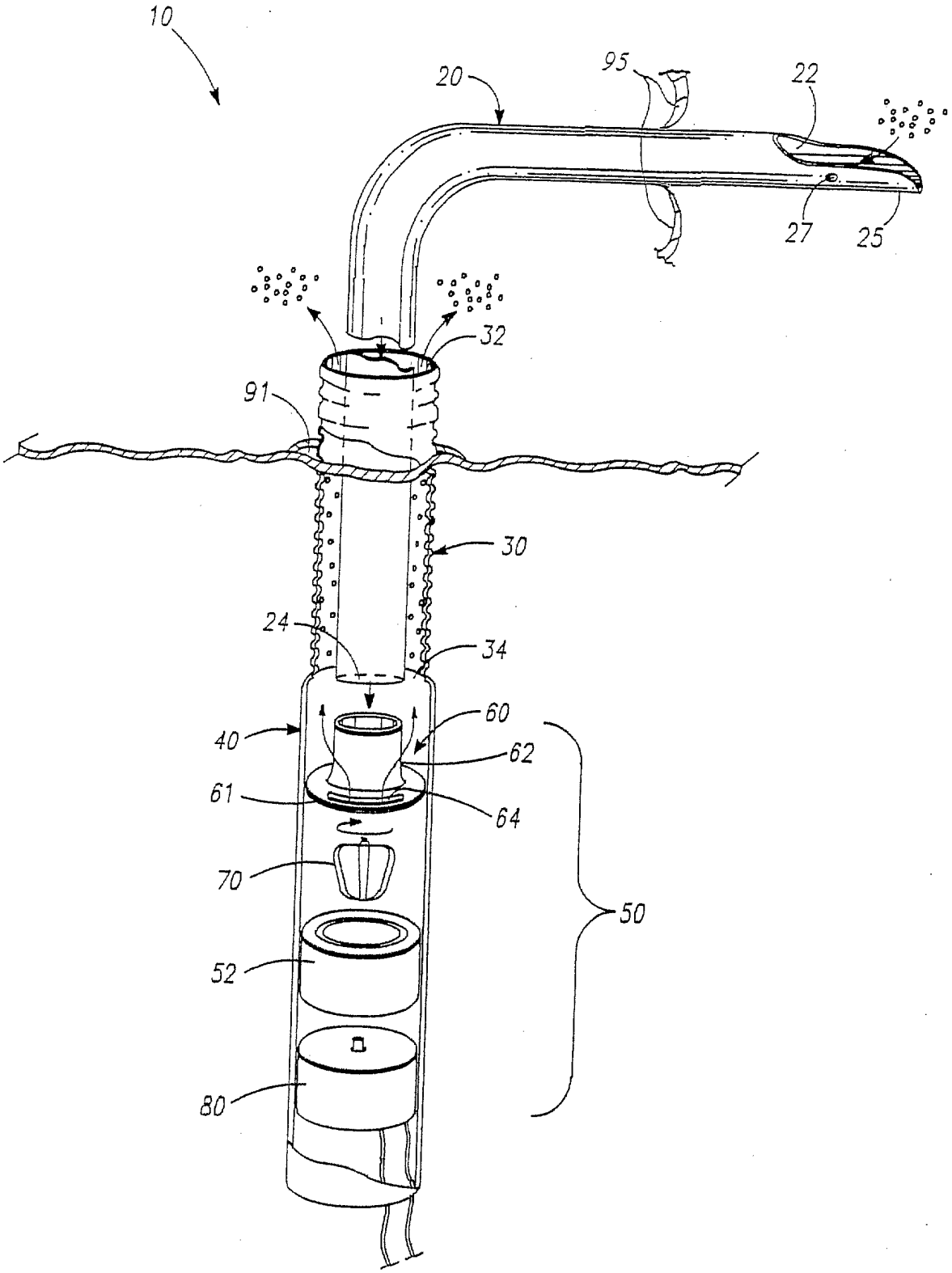

FIG.—1

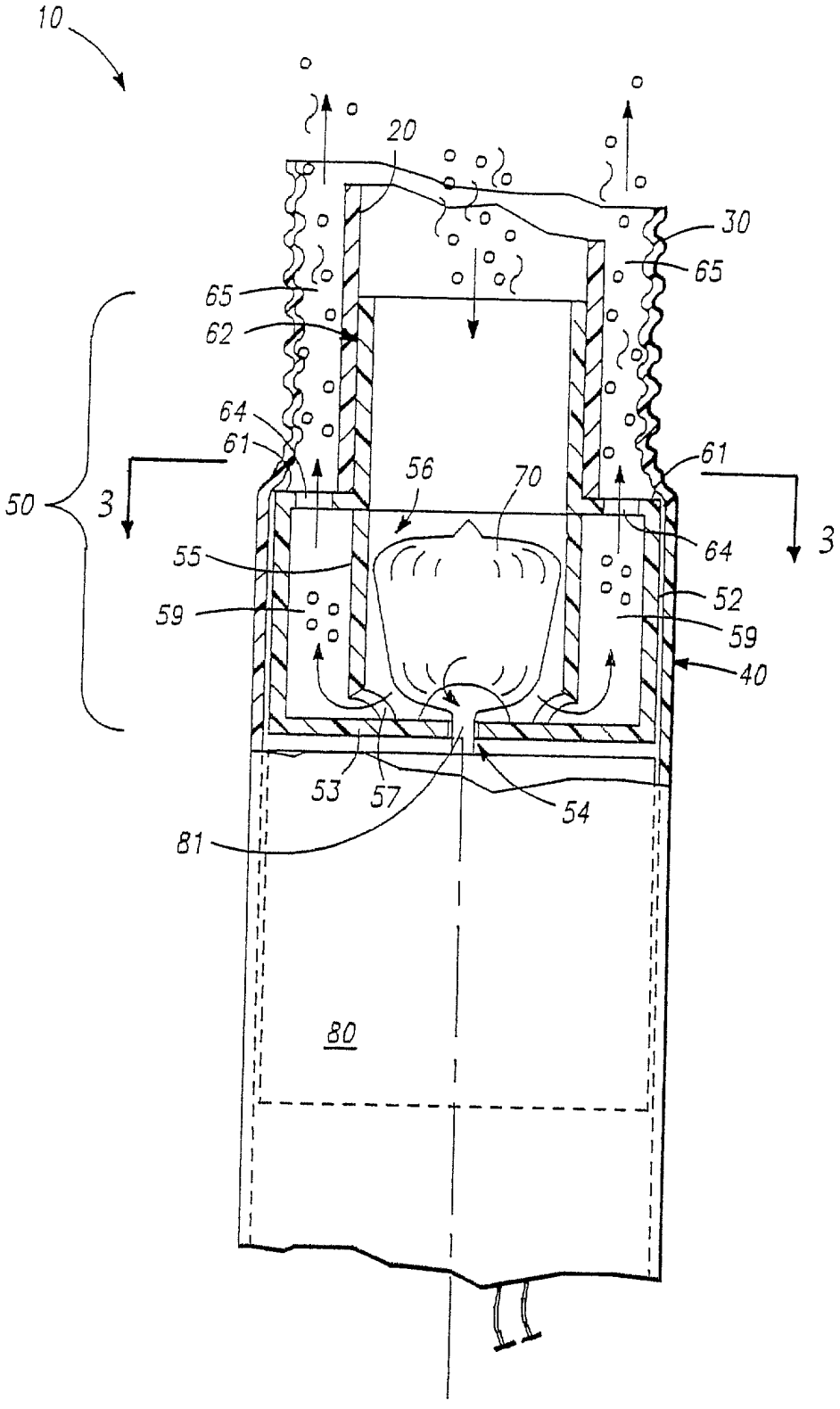

FIG.—2

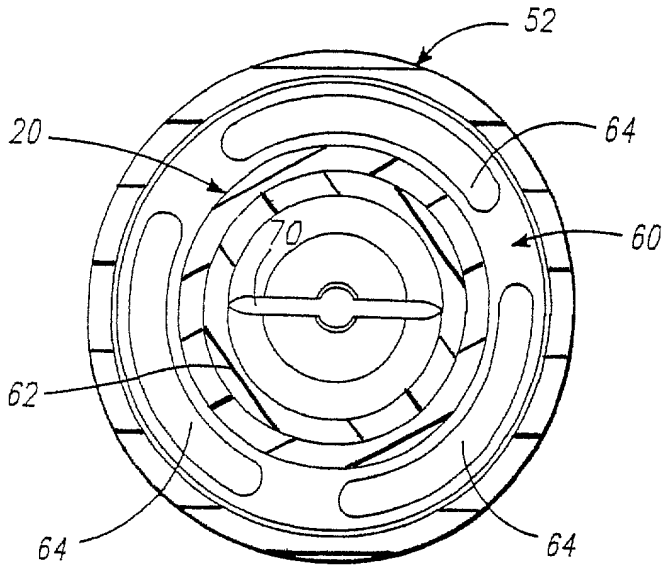

FIG.—3

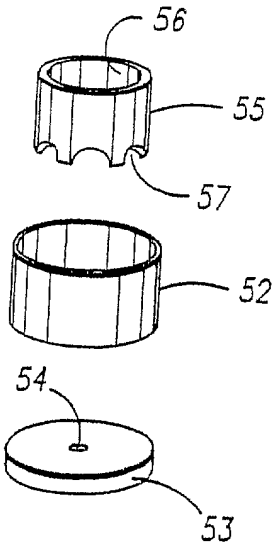

FIG.—4

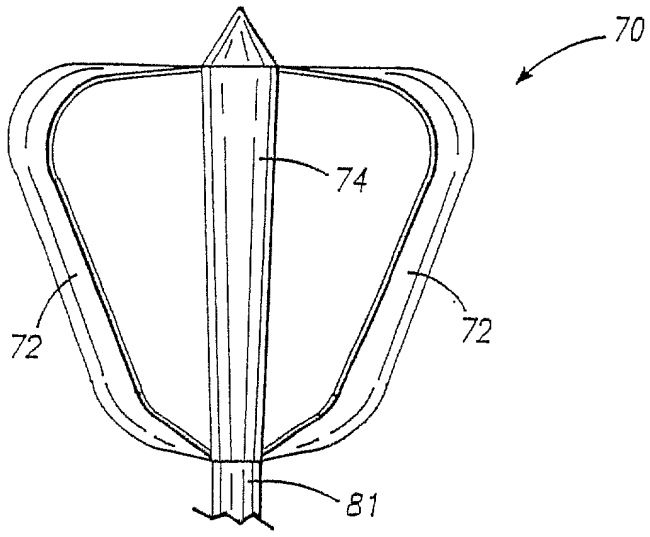

FIG.—5

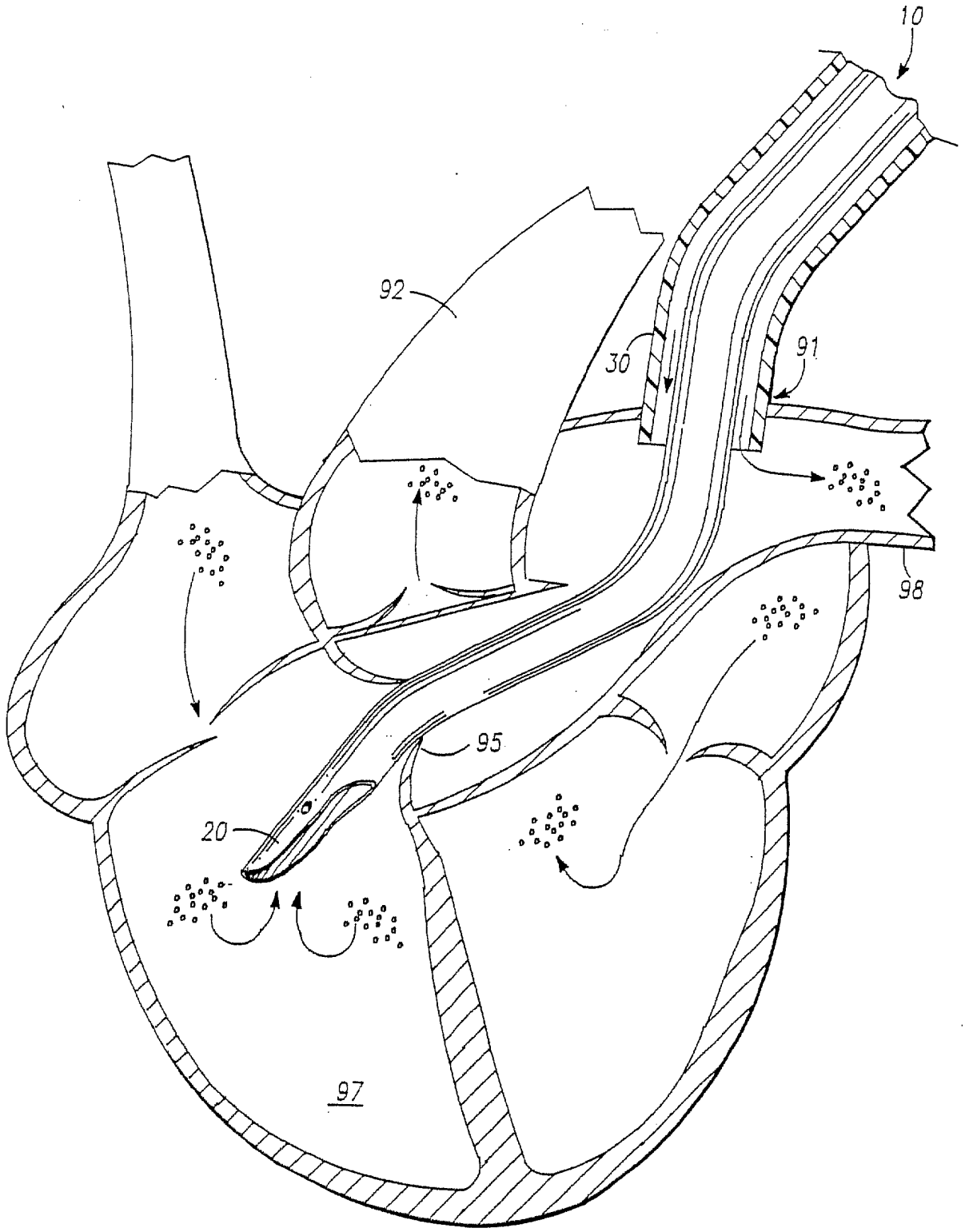

FIG.—6

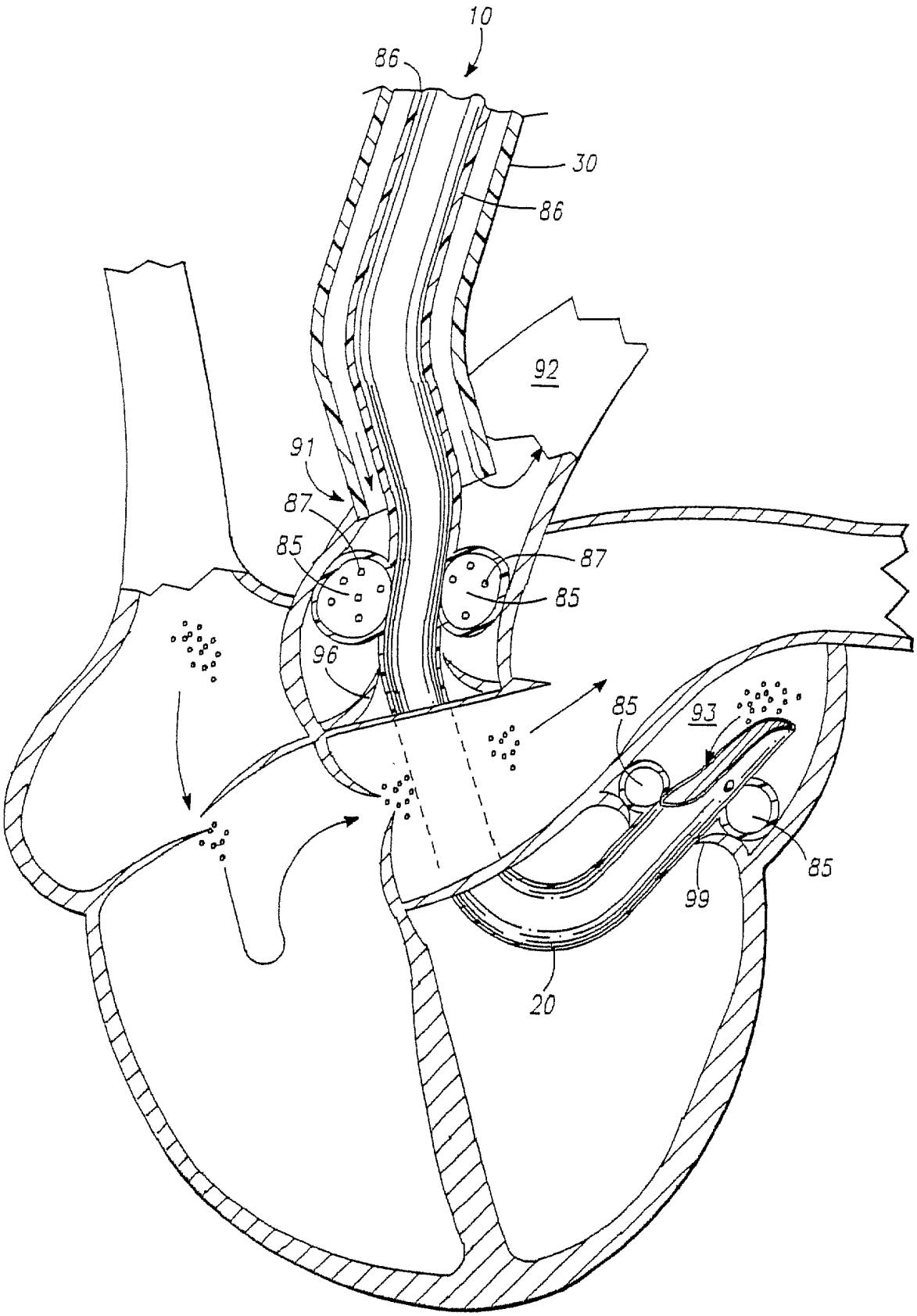

FIG.—7

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☒ Declaration Submitted with Initial Filing OR ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1. 1 6 (e)) required)

Attorney Docket Number	PA066
First Named Inventor	Aboul-Hosn
COMPLETE IF KNOWN	
Application Number	/
Filing Date	September 25, 2000
Group Art Unit	N/A
Examiner Name	N/A

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SINGLE PORT CARDIAC SUPPORT APPARATUS

(Title of the Invention)

the specification of which
☒ is attached hereto
OR
☐ was filed on (MM/DD/YYYY) _____ as United States Application Number or PCT International Application Number _____ and was amended on (MM/DD/YYYY) _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1 56

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DDNYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ **Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:**

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)	
		☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

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DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, 1 acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application,

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number *(if applicable)*
U.S. Pat. App. Ser. No. 08/891,456	July 7, 1997	

☐ **Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.**

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: ☒ **Customer Number** 23,710 *OR* ☐ **Registered practitioner(s) name/registration number listed below**

Place Customer Number Bar Code Label here

Name	Registration Number	Name	Registration Number
Jonathan Spangler, Esq.	40,182		

☐ **Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.**

Direct all correspondence to: ☒ Customer Number or Bar Code Label 23,710 OR ☐ Correspondence address below

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Country	U.S.	Telephone	(916) 375-7400, Ext. 301			Fax	(916) 375-7444

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Walid Najib	Aboul-Hosn

Inventor's Signature	Walid							Date	9/25/00
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Post Office Address									
City	Fair Oaks	State	California	ZIP	95628	Country	U.S.		

☐ Additional inventors are being named on the ____supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached here